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| 10/614,866      | 07/07/2003  | Jane Hirsh           | CP 100              | 8191             |

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/614,866

Applicant(s)

HIRSH ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 and 15-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10-27-03; 8-6-04 & 9-30-04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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### **DETAILED ACTION**

Receipt of response to restriction requirement, amendment and response dated 5-9-06 is acknowledged. Receipt of IDS dated 10-27-03; 8-6-04 & 9-30-04 is acknowledged.

Claims 14 and 30-32 have been canceled. Claims 1-13 and 15-29 are pending.

### ***Election/Restrictions***

Applicant's election without traverse of group I (claims 1-13 and 15-29) in the reply filed on 5-9-06 is acknowledged.

Upon careful consideration, the requirement to elect a species has been withdrawn. Claims 1-13 and 15-29 are considered for examination.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically teaches or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any

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inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13, 15-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,952,005 to Olsson et al ('005) in view of US 5756483 to Merkus ('483)

'005 teach a pharmaceutical composition comprising morphine, which meets the instant abuse-deterrent material. The composition is in the form of microparticles wherein the drug together with excipients is coated with water insoluble ethyl cellulose and also a water-soluble material such as HPMC (examples, col. 4- 5). The composition of '005 does not provide immediate release of the drug (see figure 1) and hence meet the claims 4-7. With respect to the degradation by the enzymes, '005 teaches coating materials that are also described in the instant application and hence the property of enzyme degradation is not separable from the coating materials of '005. '005 teach a hydrochloride salt of the drug but do not teach lipophilic derivatives such as cyclodextrin complexes.

'483 teach compositions comprising morphine, apomorphine, ergotamine etc., compounds and their administration in combination with cyclodextrin or a

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polysaccharide (abstract, examples and col. 4, lines 50-67). '483 teach that cyclodextrin and other saccharides increase the stability of the drug and thus increase their bioavailability. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to prepare morphine compositions comprising cyclodextrin or other polysaccharide so as to improve the stability and their bioavailability because "483 suggests the above advantages.

While '483 do not teach the combination of drugs as in claim 27, '483 suggest ergotamine (non- abuse deterrent) for pain (head ache, col. 1) and '005 teach morphine for its analgesic effect (also pain). Therefore, it would have been obvious been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ the combination of morphine and ergotamine with an expectation to achieve a synergistic effect because both compounds are effective against pain.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,952,005 to Olsson et al ('005) in view of US 5756483 to Merkus ('483), as applied to claims 1-13, 15-28, and further in view of US 5508542 ('542).

'005 and '483 fail to teach oxycodone of claim 29. '542 teach controlled release formulations comprising oxycodone for the management of pain. '542 teach that oxycodone is effective in pain treatment at lower amounts than morphine (col. 3-4). Thus, both '005 and '542 teach drugs for pain management and therefore it would have been obvious for one of an ordinary skill in the art at

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the time of the instant invention was made to employ oxycodone of '542 in place of morphine of '005 because '542 suggests that oxycodone is more effective than morphine because of its efficacy even at low amounts. Accordingly, a skilled artisan would have expected more effective pain management with oxycodone of '542.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
August 7, 2006